67979-12 4/17/2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1/5

APR 17 2013

Dennis Ward, Ph.D.
Syngenta Seeds, Inc. – Field Crops – NAFTA
P.O. Box 12257
3054 East Cornwallis Road
Research Triangle Park, NC 27709

Re: Bt11 x MIR162 Corn
EPA Reg. No. 67979-12
Amendment Request dated 11/17/2012, as revised by email submissions dated 4/3/2013 & 4/15/2013
Decision No. 472189

Dear Dr. Ward:

The Agency has reviewed your request to amend the subject product registration which includes the following changes to the product label:

1. Addition of two pests, the true armyworm and the lesser cornstalk borer. In support of this amendment, Syngenta submitted two studies, which were reviewed and are summarized below. A copy of the review is enclosed.
2. Removal of the restriction on application of glufosinate herbicide for weed control.
3. Addition of alternate brand names.

MRIDs 489970-01 & 489970-02.
In support of the amendment to add the true armyworm and the lesser cornstalk borer to the label, Syngenta submitted and cited studies demonstrating that Bt11 x MIR 162 should provide at least some level of control against the true armyworm and lesser corn stalk borer. Neither pest was evaluated in the context of insect resistance management (IRM), including dose and refuge considerations. Secondary pests such as these are not typically included in the IRM strategies for *Bt* corn. The Agency expects that the IRM plan in place for Bt11 x MIR 162 field corn (20% refuge with pyramided toxins) and sweet corn (pyramided toxins with crop destruction following harvest) will be sufficient to mitigate concerns with resistance developing in true armyworm and lesser corn stalk borer.

The amendment referred to above, which amends the registration issued under FIFRA section 3(c)(7)(A), is acceptable provided that you comply with the terms and conditions of the registration notice dated Dec. 22, 2011.

A stamped copy of the label is enclosed for your records.

CONCURRENCES								
SYMBOL ▶	7511P	7511P	7511P					
SURNAME ▶	Siebold	Reynolds	Allen					
DATE ▶	4/17/13	4/17/13	4/17/13					

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

If you have questions, please contact Ann Sibold by phone at 703 305-6502 or by email at sibold.ann@epa.gov.

Sincerely,

Kimberly Nesci
Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (Mail Code 7511P)

Enclosure (2)
Stamped Label
DER

3/5

Plant-incorporated Protectant Label

Bt11×MIR162 Corn

Alternate brand names: *Agrisure Viptera® 3110 Corn*
Agrisure Viptera® 3110A Corn
Bt11×MIR162 Sweet Corn
Attribute® II Sweet Corn

OECD Unique Identifier: SYN-BTØ11-1×SYN-IR162-4

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and certain lepidopteran pests.

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1) ..... ≤0.00233%*

Bacillus thuringiensis Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4) ..... ≤0.0087%*

Other Ingredients:

Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1) ..... ≤ 0.000101%*

Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4) ..... ≤ 0.00057%*

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*Percentage in whole plants on a dry weight basis

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Reg. No. 67979-12
EPA Est. No. 66736-NC-01

Syngenta Seeds, Inc. – Field Crops – NAFTA
P.O. Box 12257
3054 East Cornwallis Road
Research Triangle Park, NC 27709

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The subject registration will automatically expire at midnight on December 31, 2023.

This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

All seed corn that contains the plant-incorporated protectant sold by Syngenta Seeds, Inc. or its distributors must be accompanied by informational material (*e.g.* a bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalence guidance) prior to planting the seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

Insects Controlled or Suppressed

Field and sweet corn have been genetically transformed to produce the insecticidal proteins, Cry1Ab and Vip3Aa20, for control or suppression of the following lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Beet armyworm (*Spodoptera exigua*)
True armyworm (*Pseudelatia unipuncta*)
Black cutworm (*Agrotis ipsilon*)
Western bean cutworm (*Striacosta albicosta*)
Sugarcane borer (*Diatraea saccharalis*)
Common stalk borer (*Papaipema nebris*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Dingy Cutworm (*Feltia jaculifera*)

Insect Resistance Management

The following information regarding commercial planting of Bt11×MIR162 corn varieties must be included in the Syngenta Stewardship Guide (or equivalent document). These insect resistance management requirements do not apply to breeding, research, or increase/propagation of inbred and hybrid Bt11×MIR162 seed corn up to a total of 20,000 acres per county and up to a combined United States (US) total of 250,000 acres per registrant per year.

Refuge Requirements for Bt11×MIR162 Field Corn

- Growers must plant a structured refuge when using this product. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the Syngenta Stewardship Guide and/or in

supplements to the Stewardship Guide.

- Growers must plant a refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include separate fields, blocks within fields (*e.g.* along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within ½ mile of the Bt11×MIR162 corn field.
- If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide.
- The refuge can be treated with an insecticide for control of European corn borer, corn earworm, Southwestern corn borer, and other lepidopteran pests listed on the label, if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

The following text and graphic indicating the refuge size requirement must appear on Bt11×MIR162 seed bags or bag tags for field corn varieties.

Important grower information.
This hybrid requires you to plant:

20%
refuge

For more information, please refer
to the Syngenta Stewardship Guide

Postharvest Requirements for Bt11×MIR162 Sweet Corn Varieties

A refuge is not required for planting of sweet corn varieties. However, the crop must be destroyed after harvest.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
- The allowed crop destruction methods are rotary mowing, discing, and plow down. The crop destruction methods are intended to protect against development of insect resistance.